

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION**

MIMEDX GROUP, INC.,

Plaintiff,

v.

**TISSUE TRANSPLANT
TECHNOLOGY, LTD. d/b/a BONE
BANK ALLOGRAFTS, and TEXAS
HUMAN BIOLOGICS, LTD.,**

Defendants.

Civil Case No. 5:14-cv-719 (RCL)

MEMORANDUM OPINION

I. INTRODUCTION

In this patent case, plaintiff MiMedx sued defendants Bone Bank Allografts (“Bone Bank”) and Texas Human Biologics, Ltd. (“THB”) for infringement of United States Patent Nos. 8,597,687 (“the ‘687 Patent”) and 8,709,494 (“the ‘494 Patent”). These patents pertain to a product line of tissue grafts that are processed from human amniotic membranes derived from donated placentas. On May 2, 2017, Magistrate Judge Primomo issued a Report and Recommendation advising this Court as to the disposition of various motions filed under seal, including plaintiff’s motion for summary judgment regarding the eligibility of the ‘494 Patent, ECF No. 108, and defendants’ motion for summary judgment regarding non-infringement, ECF No. 116. On September 7, 2017, this Court adopted the analysis in Magistrate Judge Primomo’s

Report and Recommendation. Accordingly, this Court granted plaintiff's motion for summary judgment, and granted in part and denied in part defendants' motion for summary judgment.

Since this Court issued its Memorandum Opinion and Order, the parties have filed various additional motions. On October 4, 2017, plaintiff filed a motion for reconsideration of summary judgment regarding the validity of the '494 Patent, ECF No. 205. On October 25, 2017, defendants filed an opposed motion for entry of final judgment and dismissal of certain counterclaims, ECF No. 207. On September 19, 2018, based on a recent decision by the Patent Office, plaintiff filed a second motion for reconsideration, ECF No. 211, averring that the determination by the Patent Office stands in direct opposition to this Court's previous Opinion and Order and demonstrates error by this Court. In light of this second motion for reconsideration, this Court ordered on September 27, 2018, ECF No. 212, that plaintiff's prior motion for reconsideration [ECF No. 205] be denied without prejudice, and that this Court would consider the parties' positions with respect to that prior motion along with the new arguments made by the parties upon conclusion of the briefing for the second motion. The Court in its September 27, 2018 Order, ECF No. 212, also denied without prejudice defendants' motion for entry of final judgment and dismissal of certain counterclaims [ECF No. 207], stating that it will determine whether to enter final judgment upon adjudication of the second motion for reconsideration.

After consideration of these submissions, and in light of the entire record and applicable law, this Court will uphold its prior grant of defendants' motion for summary judgment concerning the invalidity of the '494 Patent on the question of whether the patent requires the substantial removal of the spongy layer. However, this Court is revisiting its Opinion and Order and denying defendants' motion for summary judgment concerning invalidity of the '494 patent

on the question of whether Vishwakarma inherently disclosed retention of the epithelial layer. As such, defendants' motion for entry of final judgment and dismissal of certain counterclaims is denied.

II. BACKGROUND

This case involves claims for infringement of the '687 Patent and the '494 Patent under the patent laws of the United States, 35 U.S.C. §§ 100, *et. seq.* Am. Compl. 1, ECF No. 17. Plaintiff MiMedx is a corporation that develops bio-medical products from placental tissues. Relevant to this case, MiMedx manufactures and markets "EpiFix" and "AmnioFix," two tissue grafts processed from the membranes of human placenta. The Patents-in-Suit cover placental tissue-based products: the '687 Patent is entitled "Methods for Determining the Orientation of a Tissue Graft," and the '494 Patent is entitled "Placental Tissue Grafts." The '687 Patent was filed on August 7, 2013, and the United States Patent and Trademark Office ("USPTO") issued the '687 Patent on December 3, 2013. The '494 Patent was filed on July 30, 2013, and the USPTO issued the '494 Patent on April 29, 2014.

On May 16, 2014, MiMedx filed suit asserting infringement on the Patents-in-Suit. Orig. Compl. 1. The original venue was the Austin Division of the Western District of Texas, but the case was transferred to the San Antonio Division in the interests of justice under 28 U.S.C. § 1404(a). ECF No. 24. In its amended complaint, MiMedx alleged that THB and Bone Bank process and prepare a line of products known as "SteriShield I," "SteriShield II," "Cygnus," and "Cygnus Solo," which are tissue graft products that infringe on Claims 1,3,4,6, and 7 of the '687 Patent and Claim 9 of the '494 Patent. Am. Compl. 1, 6. On December 1, 2015, the defendants filed a petition for *Inter Partes Review* ("IPR") by the United States Patent Trials and Appeals

Board (“PTAB”) concerning the claims at issue here.¹ The PTAB denied IPR regarding the ‘494 Patent but granted IPR regarding the ‘687 Patent. On July 7, 2016, the PTAB invalidated the ‘687 Patent pursuant to 35 U.S.C. § 103(a), finding that Claims 1-7 were obvious in light of prior art. *Tissue Transplant Tech., Ltd. v. MiMedx Group, Inc.*, Case IPR 2015-00420, Patent 8,597,687 B2, 2016 WL 3648420, at *27-28 (Patent Tr. & App. Bd. July 7, 2016). As such, the validity of the ‘687 Patent is no longer before the Court.

The instant motions concern only the validity of the ‘494 Patent with regard to Claim 9. In September 2016, the parties filed motions for summary judgment regarding the eligibility of Claim 9 of the ‘494 Patent. Pl.’s Mot. 1, ECF No. 108; Defs.’ Mot. 1, ECF No. 116. Claim 9, in its entirety, reads:

A dehydrated, laminated, placental tissue graft which is a laminate comprising two or more separated and **washed** layers which layers are selected from amnion and/or chorion wherein the layers are **directly laminated** to each other and at least one of said layers is an amnion layer which **retains an epithelial cellular layer**.

ECF No. 96 (emphasis added). Magistrate Judge Primomo issued a Report and Recommendation advising this Court as to the disposition of those motions. This Court adopted the Magistrate Judge’s Report and Recommendation, for reasons detailed more fully in this Court’s Memorandum Opinion, ECF No. 200. Relevant to the instant motions, however, the Court adopted two of Magistrate Judge Primomo’s determinations. First, the Court found that Magistrate Judge Primomo did not err in construing the terms of Claim 9 not to include a limitation requiring the removal of the spongy tissue. Second, the Court found that the Magistrate Judge correctly determined that Vishwakarma’s 1986 article does not explicitly teach removal of the epithelial cellular layer. On the basis of these findings, and others outlined in the

¹ IPR is a proceeding conducted by the PTAB to review the validity of a patent under 35 U.S.C. §§ 102 (novelty) or 103 (non-obviousness) on the basis of prior art, existing patents, or printed publications.

Court's Memorandum Opinion, this Court overruled the parties' objections to Magistrate Judge Primomo's Report and Recommendation. This Court granted plaintiff's motion for summary judgment as to subject matter patentability under 35 U.S.C. § 101, and denied defendants' motion for summary judgment insofar as it argued that the '494 Patent is invalid under § 101. The Court granted defendants' motion for summary judgment insofar as it argued that the '494 Patent is invalid as anticipated by Vishwakarma under 35 U.S.C. § 102, but denied defendants' motion for summary judgment on all other grounds.

On October 4, 2017, plaintiff filed their first motion for reconsideration of the portion of this Court's Opinion that concluded that Claim 9 of the '494 Patent is invalid as anticipated by Vishwakarma under 35 U.S.C. § 102. Plaintiff presented two arguments in this motion. First, plaintiff argued that the Court erred as a matter of law when it construed Claim 9 not to require substantial removal of the intermediate spongy layer. Second, plaintiff argued that the grant of summary judgment of invalidity was erroneous because (1) defendants failed to carry their burden to demonstrate inherent anticipation by clear and convincing evidence (the required standard to show invalidity of an issued patent), and (2) the Court improperly removed the factual question of what "denuded of mucus" means from the province of the jury. ECF No. 205. Defendants responded that plaintiff's motion argues the same premises previously considered and rejected by this Court, and so should be denied. ECF No. 206. Defendants also submitted an opposed motion for entry of final judgment and dismissal of certain counterclaims, arguing that defendants' remaining counterclaims are moot in light of this Court's grant of defendants' motion for summary judgment concerning the invalidity of Claim 9 of the '494 Patent and the PTAB's Final Written Decision invalidating all claims of '687 Patent. ECF No. 207.

On September 19, 2018, after the parties' responses and replies on these motions, plaintiffs submitted a second motion for reconsideration of the Court's prior summary judgment ruling of invalidity in light of the Patent Office's September 7, 2018 Office Action determination that the same reference on which the Court based its invalidity ruling (Vishwakarma) does not render Claim 9 of the '494 Patent invalid. The Patent Office (1) construed Claim 9 to require removal of the spongy layer, and (2) found that the Vishwakarma graft has a removed epithelial layer, but not a removed spongy layer. ECF No. 211. Defendants submitted a response in opposition to this second motion on October 3, 2018, ECF No. 213, and plaintiff replied to defendants' response on October 10, 2018, ECF No. 214. The Court now considers the motions that have been raised after this Court's Memorandum Opinion and Order on September 7, 2017, in light of plaintiff's second motion for reconsideration and the respective responses.

III. LEGAL STANDARDS

a. Relief from a Judgment or Order

Reconsideration of this Court's prior summary judgment ruling is granted under Fed. R. Civ. P. 60(b), which allows for "relief from a final judgment, order, or proceeding." Fed. R. Civ. P. 60(b). While "the Federal Rules of Civil Procedure do not provide for a motion for reconsideration, such a motion may be considered either a Rule 59(e) motion to alter or amend judgment or a Rule 60(b) motion for relief from judgment or order." *Shepherd V. Int'l. Paper Co.*, 372 F.3d 326 n. 1 (5th Cir. 2004) (internal citations omitted). In the present case, this Court's September 7, 2017 Opinion and Order should be considered a final judgment, because our grant of summary judgment with regard to the invalidity of Claim 9 of the '494 Patent effectively mooted all of the remaining claims and counterclaims at that time. To this effect, the Court entered the termination of this civil case in the docket on September 27, 2017. The current

motion for reconsideration, therefore, will be considered as a motion for reconsideration of a final judgment or order.

The Fifth Circuit has held that if such a motion “is filed within ten days of the judgment or order of which the party complains, it is considered a Rule 59(e) motion; otherwise, it is treated as a Rule 60(b) motion.” *Id.* While this Court’s current review is not *limited to* plaintiff’s second motion for reconsideration, it is *prompted by* it. As such, though this Court will also consider earlier motions such as plaintiff’s initial motion for reconsideration, ECF No. 205, it will do so under the auspices of Rule 60(b), because plaintiff’s second motion for reconsideration, which animates us now, was filed close to a year after this Court’s September 7, 2017 Opinion and Order.

Rule 60(b) provides that a court may relieve a party or its legal representative from a final judgment, order, or proceeding for “any other reason” not set forth in 60(b)(1)-(5) that justifies relief.” Fed. R. Civ. P. 60(b)(6); *see also Liljeberg v. Health Services Acquisition Corp.*, 486 U.S. 847, 848 (1988) (stating that Rule 60(b)(6) grants “broad authority to grant relief from a final judgment ‘upon such terms as are just’”). The only filing constraint under Rule 60(b) is that a motion under 60(b) must be made within a “reasonable time.” Fed. R. Civ. P. 60(c)(1). In light of the fact that the Patent Office’s Final Office Action was filed on September 7, 2018, this Court views plaintiff’s second motion for reconsideration as having been filed within a reasonable time.

b. Summary judgment

Summary judgment shall be rendered when the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine dispute as to any material fact

and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25 (1986). A properly supported motion for summary judgment will be defeated if there is a genuine dispute of material fact. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). A fact is material if it could affect the outcome of a case, and a dispute regarding a material fact is “genuine” if the evidence is such that a reasonable jury could return a verdict in favor of the nonmoving party. *Id.* To survive summary judgment, a nonmoving party must present specific facts or evidence that would allow a reasonable factfinder to find in his favor on a material issue. *Id.*; *see also* Fed. R. Civ. P. 56(c). When ruling on a motion for summary judgment, the court is required to view all inferences drawn from the factual record in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). In ruling on a motion for summary judgment, a court “may not make credibility determinations or weigh the evidence.” *Reeves v. Sanderson Plumbing Prods, Inc.*, 530 U.S. 133, 150 (2000).

c. Patent Law

Under § 282 of the U.S. Patent Act of 1952, “[a] patent shall be presumed valid,” and “[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.” 35 U.S.C. § 282. District Courts must find an invalidity defense to be proved by “clear and convincing evidence.” *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91, 95 (2011).

One such invalidity defense, relevant to this opinion, is novelty under Section 102 of the Patent Act of 1952. Section 102 provides that a person “shall be entitled to a patent unless the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention. 35

U.S.C. § 102(a)(1). Under this novelty requirement, a patent is invalid if it is anticipated by even a single piece of prior art, so long as the prior art discloses “each and every limitation of the claimed invention.” *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). Prior art may anticipate without explicitly disclosing a feature of the claimed invention if the missing characteristic “is necessarily present, or inherent, in the single anticipating reference.” *Id.* (citing *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991)). “[A]nticipation by inherent disclosure is appropriate only when the [single prior art] reference discloses prior art that must *necessarily* include the unstated limitation.” *Transclean Corp. v. Bridgwood Servs., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002). The determination of anticipation, including whether or not an element is inherent in the prior art, is a question of fact. *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375 (Fed. Cir. 2006).

IV. ANALYSIS

a. This Court correctly determined that Claim 9 did not include a limitation for removal of the spongy layer.

In this Court’s Memorandum Opinion, we determined that in light of the specification and the relevant prosecution history of the ‘494 Patent, there is no support for plaintiff’s argument that Claim 9 of the ‘494 Patent includes a limitation for the removal, or substantial removal, of the spongy tissue layer. ECF No. 200 at 17-26. Plaintiff argues that Vishwakarma does not disclose removal of the spongy layer, ECF No. 211 at 19, so if Claim 9 requires removal of the spongy layer, then Vishwakarma would not render Claim 9 invalid. At issue is whether the prior art of Vishwakarma contains all of the limitations of the Patent-in-Suit’s claim in order to render Claim 9 invalid.

This Court reached its conclusion that Claim 9 does not include a limitation for removal of the spongy layer on two grounds. First, this Court determined that it is not clear that the term “wash” in Claim 9, as plaintiff argued, requires removal of the spongy tissue. Plaintiff argued that language in the specification, describing the preferred embodiment of the invention, indicates that washing or cleaning the amnion or chorion layer requires the removal of “extraneous tissue” like the spongy layer [Pl.’s Obj. 5]. This Court was not convinced by this argument, finding that “washing” may require the removal of blood clots, but could not require the removal of the spongy layer, since there is no mention of “spongy” or “connective” tissue in the specification. ECF No. 200 at 19. Similarly, this Court determined that a related passage describing the cleaning of the amnion refers to “debris or contamination,” not to the removal of “extraneous tissue.” *Id.* at 20. Second, this Court did not construe the term “directly laminate” in Claim 9 to require the removal of all, or substantially all, of the spongy tissue layer because that limitation does not appear anywhere in the claim or the specification. *Id.* at 21. MiMedx’s objection brief itself notes that “[w]hile extraneous tissue is substantially removed, remnants of extraneous tissue, such as the spongy layer, may remain in the claimed graft,” making it clear that Claim 9 cannot require removal of all the spongy tissue. Pl.’s Obj. 10. As such, plaintiff argues that Claim 9 requires the “substantial removal” of the spongy tissue layer, pointing to the prosecution history and the written history of the preferred embodiment of the invention. In response, this Court pointed out that there is a longstanding Federal Circuit precedent against importing claim limitations from the written descriptions and prosecution history, rather than from the language of the claim itself. *Texas Digital Systems v. Telegenix, Inc.*, 308 F.3d 1193, 1204 (Fed. Cir. 2002) (compiling applicable Federal Circuit precedent). While this Court determined that the specification may direct a person having ordinary skill in the art

(“PHOSITA”) to remove extraneous tissue in some embodiments, this Court could not import those directions into the term “directly laminated,” and those directions do not broaden or narrow the scope of Claim 9. ECF No. 200 at 24-25. Therefore, because this Court found that Claim 9 does not include a limitation for removal of spongy tissue, it was not necessary for this Court to reach the question of whether the prior art in Vishwakarma disclosed a graft that required substantial removal of the spongy layer.

Plaintiff’s second motion for reconsideration now asks this Court to revisit its claim construction in light of the Patent Office’s September 7, 2018 Office Action. In the Office Action, the Patent Office adopted the Declaration of Dr. Badylak, citing it for the proposition that the amnion and/or chorion layers of the claimed graft are “substantially cleaned to remove the spongy/intermediate layer in order to achieve the ‘direct lamination’ to each other” as required by the claim. Ex. 3 at 2-3 (quoting Ex. 4 at ¶ 26), ECF No. 211. As such, plaintiff argues that the Patent Office found that “directly laminated” requires substantial removal of the spongy layer. ECF No. 211 at 16. Our Order found, by contrast, that the spongy layer is not part of the “extraneous tissue” that must be substantially removed, because the specification did not explicitly define “extraneous tissue” as including “spongy” or “connective” tissue. ECF No. 200 at 19-20. On this basis, plaintiff submits that this Court should revisit its claim construction. Specifically, plaintiff argues that reconsideration is warranted as a legal matter because the claim construction the Patent Office reached using the “broadest reasonable interpretation” (BRI) standard is narrower than the claim construction this Court reached using the *Phillips* standard, and as such, this Court’s claim construction is impermissibly broad. *See, e.g., In re CBS-System Int’l Inc.*, 832 F.3d 1335, 1341 (Fed. Cir. 2016) (explaining that “if anything, the *Phillips*

standard would result in a more narrow claim scope” than claim construction under the BRI standard).

This Court finds that it is not necessary to revisit the claim construction in its Opinion in light of the Patent Office’s *ex parte* reexamination. Unlike the claim construction conducted by the PTAB in its *inter partes* review of the ‘687 Patent, the PTO in this Office Action does little more than adopt the declaration of Dr. Badylak, without undertaking any explicit claim construction or analysis in its written decision. Even if this decision does indeed constitute a bona fide effort at claim construction, this Court is “not bound by the examiner’s finding in the *ex parte* application proceeding...particularly in light of the fact that the court heard extensive evidence on the issue in an adversary hearing.” *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1329 (Fed. Cir. 2000). Furthermore, the Federal Circuit has held that the *Phillips* standard used by the district courts in patent claim construction, not the BRI standard, constitutes “the best practices for claim construction.” *In re Translogic Technology, Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). While the purpose behind the PTO’s use of the BRI standard is to “allow the examiner and the applicant to explore the broadest possible scope of the claim,” our purpose is different; our purpose is to search “for the one ‘correct’ interpretation.” *Flo Healthcare Solutions, LLC v. Kappos*, 697 F.3d 1367, 1378-79 (Fed. Cir. 2012) (cited in Laura E. Dolbow, *A Distinction Without a Difference: Convergence in Claim Construction Standards*, 70:3 VAND. L. REV. 1071 (2017)). As such, this Court is not bound by the Patent Office’s adoption of Dr. Badylak’s construction in its *ex parte* reexamination proceeding.

Plaintiff cites to a recent Federal Circuit case, as well as a number of District Court decisions citing to that case, for the proposition that a district court’s interpretation using the *Phillips* standard cannot be broader than a PTO claim construction using the BRI standard. *See*

Facebook, Inc. v. Pragmatus AV, LLC, 582 F. App'x 864, 869 (Fed. Cir. 2014). But even assuming, arguendo, that the PTO Office Action in the present case is undertaking claim construction using the BRI standard, none of the cases plaintiff cites to resemble the posture of the present case. Here, unlike those cases, the Court has already performed its claim construction, and is now being asked, after the fact, to change its claim construction to resemble that of the Patent Office. *See, e.g., Nagravision SA v. Comcast Cable Commc'ns LLC*, No. 2:16-CV-1362-JRG, 2017 WL 5257009, at *6 (E.D. Tex. Nov. 13, 2017) (performing claim construction for the first time after the patent examiner made its interpretation); *Choon's Design Inc. v. Tristar Prods., Inc.*, No. 14-10848, 2018 WL 632107, at *5 (E.D. Mich. Jan. 30, 2018) (concluding that the PTAB's construction under the BRI standard is the same as the court's construction under *Phillips*). This Court has found no Federal Circuit precedent requiring district courts to reverse their own claim constructions in light of interpretations adopted by the Patent Office, and this Court declines to be the first to set this dangerous precedent. In fact, the Federal Circuit has conversely held that “[a] patent that has been adjudicated to be valid cannot be invalidated by administrative action, any more than a patent adjudicated to be invalid can be restored to life by administrative action.” *In re Baxter Intern., Inc.*, 678 F.3d 1357, 1368 (Fed. Cir. 2012). To that end, the “interpretation and construction of patent claims, which define the scope of the patentee’s rights under the patent, is a *matter of law exclusively for the court.*” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995) (emphasis added).

Therefore, this Court will follow the Federal Circuit’s guidance that “[t]he Examiner’s decision, on an original or reissue application, is never binding on a court. It is, however, evidence the court must consider in determining whether the party asserting invalidity has met its statutory burden by clear and convincing evidence.” *Fromson v. Advance Offset Plate, Inc.* 755

F.2d 1549, 1555 (Fed. Cir. 1985). We will, accordingly, consider the Patent Office's recognition of Dr. Badylak's testimony as evidence for us to consider in our review of our determination regarding whether the defendants have met their burden of proof. But this Court still declines to overturn its prior analysis. In its Final Office Action, the Patent Office provides this Court with no analytical reasoning on the basis of which this Court should change its decision. And the rest of the evidence, as submitted in plaintiff's first motion of reconsideration on the issue of "directly laminated," does not convince us either that we erred in our original analysis. Plaintiff's argument in their first motion for reconsideration centers on the limitation that the applicant added during the prosecution history stating that the layers "be directly laminated to each other." ECF No. 205 at 9. But it remains undisputed, even according to defendants' expert Dr. Mooradian, that the term "spongy layer" does not appear anywhere in the specification or claims of the '494 Patent. Ex. D at 75:23-76:4, ECF No. 60. This Court considers the patent's prosecution history in claim construction, as plaintiff requests that we do, but "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (internal citations omitted). Prosecution history is especially useful to "resolve the ambiguity of the specification," in cases where an ambiguous term appears in the specification but is open to differing interpretations. *See Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, 520 F.3d 1367, 1378 (Fed. Cir. 2008). But in the present case, the term spongy tissue is nowhere to be found in the specification, figures, or claims. As such, there is no ambiguous term to interpret. This Court recognizes that a claim drafter is entitled to act as his own lexicographer, but to do so, he must "clearly define terms used in the claims in the

specification.” *Sinorgchem Co., Shandong v. Int’l Trade Com’n*, 511 F.3d 1132 (Fed. Cir. 2007).

Again, in the present case, the claim drafter has not done so.

The Court recognizes plaintiff’s argument, based on its expert’s testimony, that a PHOSITA would understand that the only “extraneous tissue” left on the amnion after use of a blunt instrument, a finger, or a sterile non-particulating gauze would be remnants of the spongy layer. *See* ¶ 49, ECF No. 124-3. But we cannot base our claim construction solely on the extrinsic evidence of an expert opinion. While “extrinsic evidence may be useful to the court... it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1319 (Fed. Cir. 2005). Here, the intrinsic evidence—the claim, specification, and prosecution history—simply do not make it at all clear that there is a requirement for substantial removal of the spongy layer in all of the invention’s embodiments. This was Magistrate Judge Primomo’s conclusion, this was this Court’s conclusion, and neither the Patent Office nor plaintiff’s first motion for reconsideration has provided us with any substantial basis on which to change our interpretation.

b. This Court grants plaintiff’s motion for reconsideration on the genuine issue of material fact regarding whether Vishwakarma inherently disclosed retention of the epithelial layer

Plaintiff argues that there is a disputed issue of material fact about whether the “denuded of mucus” phrase in Vishwakarma inherently discloses retention of the epithelial layer, or whether it teaches removal of the epithelial layer. Vishwakarma is an article published in 1986 describing a standardized technique for the manufacturing of placental tissue grafts, described as an amniotic cap, for use after arthroplasty/hip surgery at a hospital in New Delhi. Ex. H, ECF No. 110-9. The relevant phrase in Vishwakarma for our purposes states that “Amnion was

separated from the chorion, and amniotic membrane, denuded of mucus, was collected in a beaker containing normal saline.” *Id.* at 69. Plaintiff argues that Vishwakarma does not inherently disclose retention of the epithelial layer, pointing to testimony from Dr. Badylak that the word “denude” or “denudation” can mean “removal of the epithelial covering from any surface.” Badylak Report ¶ 165, Ex. 10, ECF No. 170-13. Dr. Badylak argued that “denude” as used in Vishwakarma means removal of an epithelial layer. Badylak Depo. 195:2-196:3, ECF No. 170-20. Defendant’s expert, Dr. Mooradian, conceded that “denude” means to remove, but argued that it is not universally used to mean removal of an epithelial layer. Mooradian Depo. 139:10, ECF No. 124-7. As such, plaintiff argues that this is a “classic battle of the experts” and a jury should decide the question of whether Vishwakarma anticipated the ‘494 Patent. ECF No. 200 at 27.

This Court found that plaintiff attempted to create a factual dispute surrounding the word “denude” by offering testimony that this word, used alone, means to remove an epithelial cellular layer. However, in Vishwakarma, the word “denude” modifies the prepositional phrase “of mucus,” so this Court determined that the way “denude” might be defined on its own is not relevant. Addressing this, plaintiff cited Dr. Badylak’s conclusion that Vishwakarma’s use of the word “mucus” was a mistake, and Vishwakarma actually meant to use the word “mucosa,” referring to a mucus membrane with an epithelial layer. ECF No. 200 at 29. But this Court found this assertion to be conclusory and speculative because plaintiff offers no evidence that Vishwakarma’s author mistakenly used the term “mucus” instead of “mucosa,” and “[c]onclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005) (en banc). As such, this Court concluded that in the absence of a step teaching removal of epithelial layers,

those layers would be retained, and so Vishwakarma inherently discloses retention of the epithelial layer. Because the '494 Patent also does not teach the removal of the epithelial layer, Vishwakarma was deemed to anticipate Claim 9, and the Court granted defendants' motion for summary judgment insofar as it argued that the '494 Patent is invalid under 35 U.S.C. § 102. ECF No. 200 at 36.

In their second motion for reconsideration, plaintiff argues that this Court should have denied defendants' motion for summary judgment as it relates to anticipation by Vishwakarma in light of the September 7, 2018 Patent Office Action. Contrary to this Court's finding that there was no disputed evidence concerning whether Vishwakarma taught a removed epithelial layer, the Patent Office both found that Vishwakarma teaches a removed epithelial layer and credited Dr. Badylak's testimony. Specifically, the Patent Office found that the epithelial layers are not present in the amnion layers of Vishwakarma's graft, as required by Claim 9 of the '494 Patent, because the phrase "denuded of mucus" as used in Vishwakarma means the removal of the epithelial layer. Ex. 3 at 3, 5, ECF No. 211. The Patent Office credits the Badylak declaration in support of this conclusion, citing his testimony. *Id.* (citing Ex. 4 at ¶ 30-34).

In contrast with the spongy tissue issue discussed above, where this Court properly carried out its own responsibility under *Phillips* to conduct claim constructions, the epithelial layer issue tasks this Court with weighing the opinions of two experts and making a credibility determination. This alters our position in two ways. First, in such a case this Court recognizes that "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge, whether he is ruling on a motion for summary judgment or for a directed verdict." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Second, this Court must show added deference to the expertise of the

Patent Office on technical findings especially when it comes to the interpretation of prior art references. Where the PTO has made a finding, the attacker of a patent's validity has "the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents." *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984). Furthermore, "[w]here, as here, it is shown that the patent office considered prior art as close to the patented invention as any suggested to the court, the court should be extremely reluctant to substitute its opinion for the expertise of the patent office." *Ingersoll-Rand Co. v. Brunner & Lay, Inc.*, 474 F.2d 491, 496 (5th Cir. 1973).

Defendants argue that the Patent Office's decision lacks credibility because there is no evidence that the Patent Office considered this Court's opinion or Dr. Mooradian's testimony. But while defendants are correct that that this Court's Order and the exhibit containing Dr. Mooradian's testimony were omitted from MiMedx's information disclosure statements ("IDS"), defendants admit that MiMedx did submit Judge Primomo's Memorandum and Recommendation to the Patent Office, which directly cited defendants' expert Dr. Mooradian on the epithelial layer issue. ECF No. 164 at 32. We refuse to believe that the Patent Office, which regularly conducts these examinations, did not at least identify and consider Dr. Mooradian's testimony before coming to its decision. This conclusion is supported by the fact that numerous additional documents citing Dr. Mooradian's opinion were sent to the PTO by plaintiff. Ex. 19, ECF No. 214. Furthermore, the Manual of Patent Examining Procedure requires examiners to review litigation related to any patent under reexamination, MPEP § 2286, and examiners are encouraged to seek out "additional information" regarding the litigation when desirable. MPEP §

2240. Additionally, the Patent Office performed three litigation searches over the course of the '494 Patent reexamination, and all three returned this case's full litigation docket. *See* Ex's. 4-6, ECF No. 214. This Court's Order was specifically noted in both of the searches performed after the Order was issued. Ex. 5 at 54; Ex. 6 at 59, ECF No. 214. This litigation was also referenced repeatedly throughout the reexamination proceedings, including in the initial reexamination request and in the Patent Office's Order Granting Reexamination. ECF No. 211-2 at 16; ECF No. 211-3 at 7. Finally, even if the Patent Office had not seen Dr. Mooradian testimony, the office would not have credited Dr. Badylak's testimony if it did not find it to be credible enough in its own right. Therefore, defendants' attempt to call into question the legitimacy of the Patent Office's decision on this ground, ECF No. 213 at 5, carries little weight in light of the record and in light of the basic competency with which we presume the Patent Office operated.

While we decline to adopt the Patent Office's claim constructions by rote when we are not offered any reasoning either by the PTO or by plaintiff's briefing for doing so, here we award the Patent Office's determination deference because we recognize that it is not the role of this Court to make credibility determinations on summary judgment. This is especially the case where the Patent Office has sided with an expert with whom we disagreed. It remains true, as we noted above, that "[w]hile the [district] court must consider the reexamination as evidence, it is not bound by the PTO's decision." *Gator Tail, LLC v. Mud Buddy LLC*, 618 F. App'x 992, 998 (Fed. Cir. 215). Specifically, the Federal Circuit has held that this Court is "not bound by the examiner's finding in the *ex parte* application proceeding... particularly in light of the fact that the court heard extensive evidence on the issue in an adversary hearing." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1329 (Fed. Cir. 2000). But the question presently before this Court is not whether the Patent Office's determination is binding, or even particularly persuasive. The

question for this Court, when deciding whether to grant or deny a motion for summary judgment, is whether there is a genuine dispute as to any material fact, Fed. R. Civ. P. 56(a), viewing all inferences drawn from the factual record in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). Viewing all inferences in the light most favorable to MiMedx, this Court admits that there is now a genuine dispute as to material fact with regard to the prior art of Vishwakarma.

This Court's prior conviction that there is no genuine dispute over a material fact here is called into question by the Patent Office's new determination. It is further undermined by plaintiff's new emphasis on the references of Volkov, Sackier, and Dorland's Illustrated Medical Dictionary in the first motion for reconsideration, ECF No. 205. Plaintiff presents compelling evidence that in Sackier, "denuded of mucus" involves removing the epithelial cells. ECF No. 208 at 13. Plaintiff also presents compelling evidence that Volkov, which contains similar processing steps to Vishwakarma, references the term "mucous layer" rather than "mucus." ECF No. 205 at 19-20. This reading is further confirmed by Dorland's Dictionary definition of "denudation" to mean "removal of the epithelial covering from any surface." *Id.* These arguments lend more weight to the existing difficulties that plaintiff has noted in the testimony of defendants' expert, Dr. Mooradian. *See* 150:13-152:12, ECF No. 124-7 (where Dr. Mooradian speculates that Vishwakarma was referring to the spongy layer by using the word mucus because it is "mucus-like."). Indeed, Dr. Mooradian appears to have retreated from his definition of mucus when he agrees that there is no mucus in amniotic tissue. ECF No. 124-7 at 142:17-144:10. If there is no mucus in amniotic tissue, then Vishwakarma could not have been referring to denuding the amniotic tissue of mucus, and determining what Vishwakarma was in fact referring to remains an open question. As such, contrary to defendants' arguments, this Court

does not believe that the concerns we have about their own expert are a “red herring.” ECF No. 206 at 15.

This Court still recognizes that plaintiff presents no direct evidence that Vishwakarma mistakenly used the term “mucus” instead of “mucosa,” ECF No. 200 at 30. Additionally, this Court recognizes defendants’ argument that the plain language of Vishwakarma should not be changed to the plain language of Volkov, and we note defendants’ position that Sackier directly contradicts Dr. Badylak’s testimony because Sackier uses the term “denude” generally to refer to “remove.” ECF No. 206 at 12-13. But at the same time, this Court cannot deny that Dr. Badylak’s interpretation of Vishwakarma aligns with Vishwakarma’s “stated goal of maintaining mobility in between the various amniotic layers of the amniotic cap.” ECF No. 170-13 at 53-54. This Court also cannot ignore the fact that Dr. Badylak stated firmly that “one of skill in the art would also understand that there is no ‘mucus’ in a human placenta,” supporting his expert opinion that “mucus” in Vishwakarma refers to a “mucosa.” Ex. 4 at ¶ 32, ECF No. 211. What we have, at best, is competing experts with differing understandings of similar and sometimes confused terminology. In light of this newly invigorated battle of the experts, defendants have no longer clearly established their invalidity by anticipation defense by the clear and convincing standard that district courts must apply. *See Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238 (1986). We therefore reverse our prior grant of summary judgment on the question of whether Vishwakarma anticipated Claim 9 of the ‘494 Patent and, by default, deny defendants’ prior motion for entry of final judgment and dismissal of certain counterclaims.

V. CONCLUSION

In sum, plaintiff’s second motion for reconsideration will be granted in part and denied in part. For the reasons articulated above, the Court will grant plaintiff’s motion for reconsideration

regarding whether the '494 Patent is invalid as anticipated by Vishwakarma under 35 U.S.C. § 102 as to the issue of the retention or removal of the epithelial layer in Vishwakarma, but not as to the issue of the retention or removal of the spongy layer in the '494 Patent. As such, defendants' motion for entry of final judgment and dismissal of certain counterclaims is denied, and all other motions filed after this Court's Opinion and Order are rendered moot.

A separate order shall issue.

Date: December 11, 2018

A handwritten signature in cursive script, reading "Royce C. Lamberth", written over a horizontal line.

Royce C. Lamberth
United States District Judge